

**Papain**According to EC Regulations 1907/2006 (REACH),  
1272/2008 (CLP) & 2015/830

Blood and Transplant

Copy No:

Effective date:

22/09/2023

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**Safety Data Sheet****1 SECTION 1: Identification of the substance/mixture and company**

## 1.1 Product identifier

Papain.

Product Code	Product Name	UDI-DI
PN090	Papain 5mL	5055232400598
PN185	Papain 300mL (for use within NHSBT)	N/A
PN187	Papain 120mL (for use within NHSBT)	N/A
PN188	Papain 40mL (for use within NHSBT)	N/A

CAS No. : 9001-73-4

EC No. : 232-627-2

## 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: For *in-vitro* diagnostic use only

Uses advised against: Anything other than the above

## 1.3 Details of the supplier of the safety data sheet

NHSBT Reagents, 14 Estuary Banks, Speke, Liverpool, L24 8RB. United Kingdom,

Telephone: 0151 268 7157

Fax: 0151 268 7156

Email: reagents@nhsbt.nhs.uk

## 1.4 Emergency telephone number

NHSBT Reagents customer services 0151 268 7157 (Monday to Friday 9am to 5pm. Calls will be forwarded to an answering machine outside of these hours)

Further information available from: [www.blood.co.uk/reagents](http://www.blood.co.uk/reagents)

Languages spoken: English

**2 SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

Not classified as hazardous for supply/use according to Regulation (EC) 1272/2008 (CLP).

## 2.2 Label elements

No Hazard Pictogram(s), Signal Word(s), Hazard Statement(s) or Precautionary Statement(s) have been assigned according to Regulation (EC) 1272/2008 (CLP).

## 2.3 Other hazards

Papain, L-cysteine (4 g/l) and dipotassium EDTA (0.4g/l) are classified as irritants, but at the concentration used within this reagent are not associated with any hazards.

**3 SECTION 3: Composition/information on ingredients**

## 3.1 Substances

N/A

## 3.2 Mixtures

Papain is produced from an extract prepared from crude Papain in M/15 phosphate buffer (Ph 5.3) which contains the following:

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Component	Approximate Concentration (%)	CAS number	EC number	Hazard
Sorbitol	2.2	50-70-4	200-061-5	No hazards
Sodium phosphate monobasic dihydrate	1.2	13472-35-0	603-853-2	No hazards
Sodium phosphate dibasic dodecahydrate	0.7	10039-32-4	231-448-7	No hazards
L-cysteine hydrochloride	0.4	52-89-1	200-157-7	Eye Irrit. 2; H319: Causes serious eye irritation.
Papain	0.1	9001-73-4	232-627-2	Skin Irrit. 2; H315: Causes skin irritation. Eye Irrit. 2; H319: Causes serious eye irritation. STOT SE 3; H335: May cause respiratory irritation Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
K2 EDTA	0.04	25102-12-9	2001-94-7	Acute Tox. 4; H332: harmful if inhaled. STOT RE 2; H373: May cause damage to organs through prolonged or repeated exposure.
Sodium hydroxide	Varies(<1)	1310-73-2	215-185-5	Skin Corr. 1A; H315: Causes skin irritation. Eye Dam. 1; H319: Causes serious eye irritation (0.5% - 2% only)

None of the products at the concentration used within this reagent are associated with any hazards.

#### 4 SECTION 4: First aid measures

##### 4.1 Description of first aid measures

Eye contact: Flush eyes with water for at least 15 minutes while holding eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

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**Skin contact:** Wash affected skin with soap and water. Remove contaminated clothing and wash clothing before reuse. If irritation (redness, rash, blistering) develops, get medical attention.

**Ingestion:** Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

**Inhalation:** Not applicable.

- 4.2 Most important symptoms and effects, both acute and delayed  
All known important symptoms are described in Section 3.
- 4.3 Indication of any immediate medical attention and special treatment needed  
No special treatment indicated. Treat Symptomatically.

## 5 SECTION 5: Firefighting measures

- 5.1 Extinguishing media  
Non-Flammable. Use extinguishing media appropriate to the surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture  
None known.
- 5.3 Advice for firefighters  
Fight fire with normal precautions from a reasonable distance.

## 6 SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures  
Use personal protective equipment during removal of spillages.
- 6.2 Environmental precautions  
Control spillage in accordance with local regulations.
- 6.3 Methods and material for containment and cleaning up  
Wipe up spillage with absorbent paper towels. Wash spill site after material pick up is complete
- 6.4 Reference to other sections  
See section 8 and 13 for disposal information

## 7 SECTION 7: Handling and storage

- 7.1 Precautions for safe handling  
When handling product use personal protective equipment as required. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned.  
Protect from contamination.
- 7.2 Conditions for safe storage, including any incompatibilities  
Store the reagent below -20°C in the original container/packaging.
- 7.3 Specific end use(s)  
See section 1.2

## 8 SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters  
None of the products at the concentration used within this reagent are associated with any hazards. No monitoring procedures required

### 8.2 Exposure controls

When handling product use personal protective equipment as required. Avoid contact. Keep good hygiene and housekeeping measures.

## 9 SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- (a) Appearance: A clear liquid with proteolytic enzyme activity.
- (b) Odour: Odourless
- (c) Odour threshold: Not established
- (d) pH: Not established
- (e) Melting point/freezing point: Not established
- (f) Initial boiling point and boiling range: Not established
- (g) Flash point: Not established
- (h) Evaporation rate: Not established
- (i) Flammability (solid, gas): Not established
- (j) Upper/lower flammability or explosive limits: Not applicable
- (k) Vapour pressure: Not established
- (l) Vapour density: Not established
- (m) Relative density: Not established
- (n) Solubility(ies): Miscible with water
- (o) Partition coefficient: n-octanol/water: Not established
- (p) Auto-ignition temperature: Not established
- (q) Decomposition temperature: Not established
- (r) Viscosity: Not established
- (s) Explosive properties Not explosive
- (t) Oxidising properties: Not oxidising

### 9.2 Other information

No further information available

## 10 SECTION 10: Stability and reactivity

### 10.1 Reactivity

Stable under normal conditions

### 10.2 Chemical stability

Stable for stated expiry date of the product when stored below  $-20^{\circ}\text{C}$ .

Papain should be disposed of 24 hours after thawing.

Do not re-freeze.

Do not use if product is not frozen on receipt

Do not use if the solution is turbid or there is evidence of gelling.

### 10.3 Possibility of hazardous reactions

None under normal processing and use.

### 10.4 Conditions to avoid

Keep away from heat and direct sunlight.

### 10.5 Incompatible materials

There are no known materials that could react with this product to produce a hazardous situation.

### 10.6 Hazardous decomposition products

There are no known hazardous decomposition products produced.

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**11 SECTION 11: Toxicological information****11.1 Information on toxicological effects**

(a) acute toxicity;

Ingestion: based on available data, the classification criteria are not met for this mixture.

(b) skin corrosion/irritation; based on available data, the classification criteria are not met for this mixture.

(c) serious eye damage/irritation; based on available data, the classification criteria are not met for this mixture.

(d) respiratory or skin sensitisation; based on available data, the classification criteria are not met for this mixture.

(e) germ cell mutagenicity; based on available data, the classification criteria are not met for this mixture.

(f) carcinogenicity; based on available data, the classification criteria are not met for this mixture.

(g) reproductive toxicity; based on available data, the classification criteria are not met for this mixture.

(h) STOT-single exposure; based on available data, the classification criteria are not met for this mixture.

(i) STOT-repeated exposure; based on available data, the classification criteria are not met for this mixture.

(j) aspiration hazard: based on available data, the classification criteria are not met for this mixture.

See section 3 for individual component hazard classification.

**12 SECTION 12: Ecological Information****12.1 Toxicity**

Based on available data, the classification criteria are not met for this mixture. (see section 3 for individual component hazard classification)

**12.2 Persistence and degradability**

Not established. Predicted to be unlikely.

**12.3 Bio accumulative potential**

Not established. Predicted to be unlikely.

**12.4 Mobility in soil**

This product has high mobility in soil. Miscible with water.

**12.5 Results of PBT and vPvB assessment**

Not classified as PBT or vPvB. None of the substances in this product fulfil the criteria for being regarded as a PBT or vPvB substance.

**12.6 Other adverse effects**

None known.

**13 SECTION 13: Disposal Considerations****13.1 Waste treatment methods**

The product and any contaminated packaging should be disposed in accordance with local state or national legislation.

**14 SECTION 14: Transport Information**

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods.'

## 14.1 UN number

Not assigned ADR/RID, IMDG or IATA/ICAO numbers.

## 14.2 UN proper shipping name

Not assigned ADR/RID, IMDG or IATA/ICAO numbers.

## 14.3 Transport hazard class(es)

Not assigned ADR/RID, IMDG or IATA/ICAO numbers.

## 14.4 Packing group

Not assigned ADR/RID, IMDG or IATA/ICAO numbers.

## 14.5 Environmental hazards

Not assigned ADR/RID, IMDG or IATA/ICAO numbers.

## 14.6 Special precautions for user

See section 2

## 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not Applicable

**15 SECTION 15: Regulatory information**

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product does not contain substances subject to EU authorisation or restriction of use.

This safety datasheet was prepared in accordance with the requirements of EC regulation 1907/2006 (REACH) (Article 32, Annex II) and 1272/2008 (CLP) & 2015/830

## 15.2 Chemical safety assessment

None.

**16 SECTION 16: Other information**

Amendments from the previous version of this SDS are in purple text.

LEGEND	
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical abstracts service
CLP	Classification, labelling and packaging of substances and mixtures
EC	European Commission
EDTA	Ethylenediaminetetraacetic acid
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)

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MARPOL	International Convention for the Prevention of Pollution from Ships
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bio accumulative and Toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety data sheet
STOT	Specific target organ toxicity
vPvB	Very persistent and very bio accumulative

### Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be conducted by professionally trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. NHSBT reagents gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. NHSBT reagents accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

### Training advice

Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

### Date of First Issue

18/07/2008